Docket No.: 29985/01-028
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	)	
Ehr et al.	)	Confirmation No.: 1216
	)	
Application No.: 10/027,154	)	Art Unit: 3736
	)	
Filed: December 20, 2001	)	Examiner: Jonathan M. Foreman
	)	
For: Pressure-Sensing Guidewire and Sheath	)	
	)	

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Notice of Appeal filed on August 22, 2007, in connection with the above-identified patent application, Appellant respectfully submits this Appeal Brief in accordance with 37 C.F.R. §41.37. This Brief is timely filed within two month from the receiving date of the Notice of Appeal by the Office.

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This Appeal Brief contains the following items in the order set forth below (37 C.F.R. §41.37(c)):

I. REAL PARTY IN INTEREST

The real party in interest in the application on appeal is SciMed Life Systems, Inc., the assignee of the present application, which is a wholly owned subsidiary of Boston Scientific Scimed, Inc. An assignment assigning rights in the present application to SciMed Life Systems, Inc was recorded in the United States Patent and Trademark Office at Reel 012674, Frame No. 0098.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellant, Appellant's legal representative, or Assignee, which will directly affect or be directly affected by, or have bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Currently, claims 10, 13-14, 16, and 19 are pending All pending claims stand rejected in view of the cited prior art The rejections asserted against claims 10, 13-14, 16, and 19 are hereby appealed. The currently pending claims are reproduced in the Claims Appendix to this Brief.

IV. STATUS OF AMENDMENTS

No amendment to pending claims 10, 13-14, 16, and 19 was submitted in response to the latest Office action dated June 22, 2007 because, contrary to the Examiner's assertion, the subject matter specifies in each of the pending claims is not rendered obvious by the combination of prior art suggested by the Examiner. A response was filed August 22, 2007, but no amendments were made and thus none are currently outstanding.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present disclosure is a medical device for use in angioplasty. More specifically, angioplasty has become a common place method of treating vascular disease. With vascular disease, plaque or other cells attach themselves to the interior of a blood vessel wall and thereby form a stenosis or occlusion. Depending upon the severity of the occlusion, angioplasty will be performed to dilate or otherwise open the stenosis to allow for greater blood flow and thus decrease the pressure within that particular vessel. This is typically performed by navigating a balloon catheter through the artery to the site of the occlusion, and then inflating the balloon (see specification, page 1, lines 15-23).

However, as these occlusions are nested deep within the tissue of the patient, it is advantageous to provide a mechanism by which the severity of the occlusion can be determined prior to performing any invasive surgery or angioplasty. The present disclosure allows for this function to be effectively accomplished. Specifically, the pending disclosure sets forth a medical device which measures the pressure within a vascular structure, particularly small blood vessels and arteries, where it is desired to perform an angioplasty. Once introduced, the device is able to measure blood pressure on both sides of the stenosis. If the blood pressure differential between the two sides is of a sufficient level, a physician will know that it is appropriate to perform an angioplasty and if the pressure differential is not of a particular level, other less invasive treatments can be considered (see specification, page 1, line 29 – page 2, line 7).

The claimed medical device is designed to be navigated through a clotted blood vessel as illustrated in Figures 1-3 of the pending application. One structural feature which allows for this function is the provision of a slidable tube within a sheath wherein the tube has one relatively long opening, and the sheath has two spaced apart openings (see specification, page 3, lines 7-17). Another is the cross-sectionally circular, low profile shape of the device as

recited in the rejected claims (see specification, page 2, line 28 – page 3, line 4). Those claims are summarized below.

The currently pending claims of this application include two independent claims 10 and 16, of which claim 10 is broader than, and encompasses, claim 16. Appellant hereby submits that all pending claims stand and fall with independent claim 10.

Independent claim 10 specifies a device for measuring blood pressure within a vascular structure, comprising: (1) a tubular sheath sized for insertion into the vascular structure, the tubular sheath including an open proximal end, a closed distal end, at least two axially spaced apart openings in a sidewall thereof, and an inside peripheral surface; (2) an elongated tube disposed within the tubular sheath and including an open proximal end, a closed distal end, a single opening in a sidewall thereof and an outside peripheral surface engaging the inside peripheral surface of the tubular sheath about the entire outside peripheral surface of the elongated tube, wherein the elongated tube being frictionally received within the tubular sheath thereby allowing the opening of the elongated tube to be selectively aligned with one of the axially spaced apart openings of the tubular sheath at a time and so that engagement between the inside peripheral surface of the tubular sheath and the outside peripheral surface of the elongated tube substantially prevents fluid communication between the inside peripheral surface of the tubular sheath and the outside peripheral surface of the elongated tube and through the tubular sheath; and (3) a pressure transducer in fluid communication with the elongated tube proximal end so that blood from the vascular structure is communicated to the pressure transducer when the elongated tube opening is aligned with one of the tubular sheath openings, thereby to directly measure the blood pressure, wherein the blood pressure measuring device has a distal portion that is inserted into the vascular structure, and wherein an exterior surface of the distal portion of the blood pressure measuring device has a cross-sectional profile of a single circle.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The two issues presented on this appeal are:

(1) Whether independent claim 10 is unpatentable under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,168,703 ("Kenigsberg") in view of U.S. Patent Application Publication No. 2002/0049402 ("Peacock, III"); and

(2) Whether extensive modification of Kenigsberg's water-infusing diagnostic tool for use in a gastroesophageal track is within the ability of those having ordinary skill in the art when contemplating a device for measuring blood pressure within a vascular structure specified in the pending claims at issue

VII. ARGUMENT

Independent claim 10 is patentable over the suggested combination of Kenigsberg and Peacock, III This rejection should be overturned because a *prima facie* case of obviousness under 35 U.S.C. § 103 has not been established, even with the Examiner's extremely broad interpretation of the cited references.[1]

I. The combination of Kenigsberg and Peacock, III does not teach or suggest each and every element of independent claim 10.

As the Board will note, the claimed device for measuring blood pressure within a vascular structure includes at least the following two elements: (1) a tubular sheath having a closed distal end and an inside peripheral surface; and (2) a distal portion, the exterior of the distal portion having a cross-sectional profile of a single circle. Neither of those elements is disclosed or suggested by the combination of Kenigsberg and Peacock, III.

(a). The combination of Kenigsberg and Peacock, III does not teach or suggest a tubular sheath having a closed distal end.

Throughout the prosecution of this application the Examiner has admitted that "Kenigsberg discloses the tubular sheath as preferably having an open distal end (Col. 2, line

[1] To establish a *prima facie* case of obviousness, three basic criteria must be met First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of a plurality of references Finally, there must be a reasonable expectation of success The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on the Applicant's own disclosure. See In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir 1991). *See also* MPEP § 2143. The Examiner bears the burden of establishing a *prima facie* case of obviousness and "can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 5 U.S.P.Q 2d 1596, 1598 (Fed Cir. 1988) To support a conclusion that a claimed combination is obvious, either: (a) the references must expressly or impliedly suggest the claimed combination to one of ordinary skill in the art, or (b) the examiner must present a convincing line of reasoning as to why a person of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *See In re Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Int. 1985)

60) and fails to disclose the distal end being closed." *See* page 3 of Office action dated June 22, 2007 Nevertheless, the Examiner has maintained that it would have obvious to one of ordinary skill in the art to modify the open distal end of the tubular sheath (12) to be a closed distal end with an opening adjacent thereto because (a) Kenigsberg teaches that the elongated tube (22) as well as the tubular members (32, 38) could each have a closed distal end with an opening adjacent thereto; and (b) Kenigsberg teaches that it is desirable to keep the elongated tube from extending past the distal end of the sheath (page 3 of Office action dated June 22, 2007)

Appellant disagrees with this assertion. The mere fact that the elongated tube (22) and tubular members (32, 38) can be modified to have closed distal ends with openings adjacent thereto does not automatically constitute an implicit teaching of similar modification of the tubular sheath (12). Appellant submits that the elongated tube (22) and the tubular members (32, 38) are structurally and functionally similar in that each serves as a flow passage for water infused therethrough and each is connected to a strain gauge for measuring the resistance of the outflow of the infused water (col. 4, lines 38-41 and 45-50)

The tubular sheath (12), on the other hand, simply serves to provide a stationary exterior cover for the elongated tube (22) so that the movement of the elongated tube (22) along the gastroesophageal track (44) can be accomplished without disturbing the patient or affecting the accuracy of the pressure readings at various selected positions within the gastroesophageal track (44) (col. 5, lines 52-61). No water is infused *through* the sheath (12). Nor is the sheath connected to any pressure measuring gauge. Consequently, the sheath (12) is structurally and functionally different from the elongated tube (22) and the tubular members (32, 38) Appellant respectfully submits that a specific structural modification of one component cannot be properly transferred or extrapolated to another structurally and

functionally different component without any explicit or implicit teaching from the specification. *See* footnote on pages 9.

Presumably realizing the lack of justification for the proposed modification, the Examiner further asserts that such modification is obvious because Kenigsberg teaches that it is desirable to keep the elongated tube from extending past the distal end of the sheath (col. 3, lines 28-31) Appellant, again, has to disagree with the Examiner's assertion because instead of closing the distal end (14) of the sheath (12) as suggested by the Examiner, Kenigsberg explicitly teaches that the overextension of the elongated tube (22) past the distal end (14) of the sheath (12) can be prevented by sizing the length of the elongated tube (22) so that extension beyond the distal end (14) can be halted by the contact of the tapered end (26) with the manipulating body (16) (col. 3, lines 32-37).

According to Kenigsberg, "[t]his will thereby *insure* that open end 24 of the probe 22 will be slidable only within the hollow interior of the sleeve 12 and not beyond its distal end 14." (Col 3, lines 37-40, emphasis added by Appellant). Clearly, the problem of overextension is successfully solved by Kenigsberg through conveniently sizing the length of the elongated tube (22) and thus cannot serve as proper motivation for the modification proposed by the Examiner

Thus, the modification of the distal end of the sheath proposed by the Examiner is not disclosed or suggested by Kenigsberg. Nor is the modification properly inferred from the broadest interpretation of Kenigsberg's disclosure by one of ordinary skill in the art As a result, Appellant submits that the cited prior art does not teach or suggest a tubular sheath having a closed distal end, as recited in independent claim 10.

(b). The combination of Kenigsberg and Peacock, III does not teach or suggest the exterior of the distal portion of a medical device having a cross-sectional profile of a single circle.

The distal end of Kenigsberg's device includes the sheath (12), the elongated tube (22) concentrically disposed within the sheath, and the tubular member (32) attached parallel to the exterior surface of the sheath. Therefore, unless the tubular member (32) is detached from the exterior surface of the sheath, Kenigsberg's device cannot meet the limitation of having a distal portion, wherein the exterior of the distal portion has a cross-sectional profile of a single circle, as recited in independent claim 10.

Presumably realizing this deficiency, the Examiner boldly asserts that "Kenigsberg discloses a distal portion of the [blood pressure measuring] device having an exterior surface having a cross-sectional profile of a single circle" (Office action dated June 22, 2007), which is based merely on Kenigsberg's broad and nonspecific statement that "the member 32 maybe located within a suitably *modified* sheath" (col. 3, lines 62-63, emphasis added by Appellant)

The same assertion was also made in a previous Office action and was properly rebutted by Appellant in a response dated June 4, 2007, in which Appellant argued that it is not obvious for one of ordinary skill in the art to accommodate the hypothetical relocation of the tubular member (32) from its original position to within the sheath while meeting each and every limitation recited in independent claim 10. The cross-sectional profile of Kenigsberg's device is illustrated in FIG. 2, a copy of which is attached below for reference purposes.

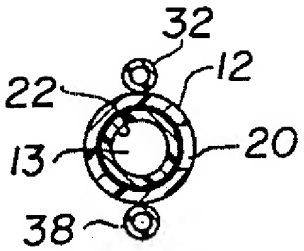

FIG.2

In that response, Appellant submitted two possible configurations that would be apparent to one of ordinary skill in the art to accommodate the positioning of the tubular member (32) within the sheath (12) without changing the circular cross-sectional profile thereof: a side-by-side configuration wherein the tubular member (32) is positioned alongside the elongated tube (22) as illustrated in FIG. A below; and a concentric configuration wherein the tubular member (32) is disposed within the interior of the elongated tube (22) as illustrated in FIG. B below.

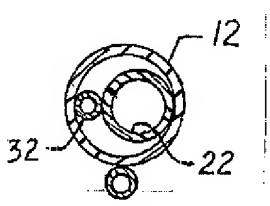

FIG. A

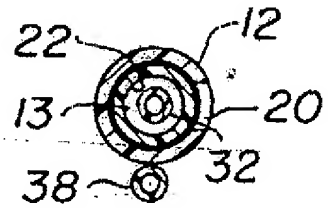

FIG.B

As discussed in that response, both of those configurations would either vitiate one or more limitations recited in independent claim 10, or render Kenigsberg's device inoperable, and thus cannot serve as proper modifications of Kenigsberg to render the subject matter specified in independent claim 10 obvious.

More specifically, in the side-by-side configuration, the inclusion of the tubular member (32) within the interior of the sheath (12) alongside the elongated tube (22) would

render the engagement between the outside peripheral surface of the probe and inside peripheral surface of the sheath recited in independent claim 10 geometrically impossible. Therefore, this modification of Kenigsberg's device cannot render the amended independent claims obvious because it fails to teach each and every limitation recited in independent claim 10

The concentric configuration, on the other hand, is not a viable modification because such modification renders Kenigsberg's device inoperable. More specifically, the purpose of the tubular member (32) in Kenigsberg's device is for continuous measuring of the pressure inside the stomach as a real-time reference to the pressure of the gastroesophageal track measured by the elongated tube (22) when the elongated tube moves along the track.

Such operating mechanism, however, is clearly incompatible with the concentric configuration illustrated in FIG. B because the reference member, when disposed within the interior of the elongated member having a closed end (see page 2 of Office action dated June 22, 2007), cannot be in constant contact with the inside of the stomach as the elongated tube moves along the track, and therefore cannot continuously measure the pressure of same Consequently, there can be no suggestion or motivation to modify Kenigsberg according to the concentric configuration because under MPEP 2143.01, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See also *In re Gordon*, 733 F 2d 900, 221 USPQ 1125 (Fed Cir 1984).

To maintain his rejection, the Examiner has once again relied on the vague and broad disclosure of Kenigsberg in order to conjure up a modification of Kenigsberg's device that reads on the claimed invention. In particular, by citing a schematic Fig. 1B of Peacock, III, the Examiner has asserted that "a third configuration, one where a lumen is formed in the

sidewall of the sheath as taught by Peacock, III et al , would be obvious modification to the device as disclosed by Kenigsberg". The rationale behind this modification, according to the Examiner, is to "lead to operability of the device as well as the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath" (page 5 of Office action dated June 22, 2007).

Appellant disagrees Appellant first submits that the rationale proffered by the Examiner is a classic hindsight of the claimed invention. It is improper to use hindsight to combine the prior art references, as noted in *Orthopedic Equipment Co. v. United* States, 217 U.S.P.Q 193, 199 (Fed. Cir 1983), which stated that "[i]t is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." The Federal Circuit has observed that the use of hindsight can be a trap for the unwary, particularly when considering simple inventions, in noting:

> Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.

In re Dembiczak, 50 U.S.P.Q 2d 1614, 1617 (Fed Cir. 2000) (citations mitted, emphasis added by Appellant) It is important to consider the invention as a whole when determining obviousness; it is improper to simply focus on the differences between the claimed subject matter and the prior art *Hybritech Inc v Monoclonal Antibodies*, 802 F 2d 1267, 231 U.S.P.Q. 91 (Fed Cir 1986). The proper inquiry when determining nonobviousness is whether "there is something in the prior art as a whole *to suggest* the desirability, and thus the obviousness, of making the combination " *Fromson v Advance Offset Plate, Inc* , 755 F.2d 1549, 1556, 225 U.S.P.Q. 26, 31 (Fed. Cir 1985) (emphasis in original).

Here, the Examiner's rationale to modify of Kenigsberg's device in view of Peacock, III to "lead to operability of the device as well as the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath" is clearly guided by the claimed invention and not by the prior art references and the then-accepted wisdom in the field. *See In re Dembiczak, supra*. Kenigsberg's device is perfectly operable. Moreover, the limitation that "the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath" is contemplated only by the claimed invention, and not by Kenigsberg or Peacock, III. Not only is Kenigsberg completely silent with respect to the engagement of the tube against the sheath, Kenigsberg explicitly discloses that "movable probe 22 is ...*sized* for relatively longitudinal *frictionless* sliding movement within the interior 13 of the sheath 12" (col. 3, lines 18-20, emphasis added), indicating that engagement may not be necessary or even desirable. Nor is this limitation contemplated in Peacock, III (see FIGs. 2B, 2C, 4C, 5B). Thus, it is clear that the modification suggested by the Examiner is guided not by the cited prior art or knowledge in the field of invention, but by the impermissible hindsight reasoning prohibited by the patent laws.

Second, Appellant submits that the modification of Kenigsberg in view of Peacock, III is oversimplified by the Examiner in the Office action, presumably in order to make such modification within the reach of one having ordinary skill in the art. The tubular member (32) is not a simple lumen because "[m]ember 32 is an elongated, hollow tube" (col. 3, lines 58-59) with a proximal end that "extends flexibly *away* from the sheath 12" (col. 4, lines 2-3, emphasis added by Appellant). As a result, the incorporation of the member (32) into the tubular wall of sheath (12) proposed by the Examiner would require extensive modification of the structure of the sheath (12). Moreover, according to the drawings of Kenigsberg, the diameter of the tubular member (32) is significantly larger than the tubular wall of the sheath (12). Hence, the diameter of the tubular member (32) would need to be decreased

substantially in order to accommodate the modification proposed by the Examiner. How a person of ordinary skill in the art, and ordinary common sense and creativity, would attempt to position the tubular member (32) within the tubular wall of the sheath (12) by substantially shrinking the diameter of the tubular member (32) and structurally modifying the sheath (12) without any motivation and guidance from Kenigsberg is beyond the understanding of Appellant and his attorneys

Therefore, Appellant respectfully submits that although the third configuration suggested by the Examiner is not theoretically impossible, it would not be obvious to one of ordinary skill in the art. As a result, the combination of Kenigsberg and Peacock, III does not teach a device having a distal portion, the exterior of the distal portion having a cross-sectional profile of a single circle, as required by independent claim 10

In summary, independent claim 10, and claims 13-14, 16, and 19 depended thereupon, are not rendered obvious over the prior art cited by the Examiner because the combination of Kenigsberg and Peacock, III fails to teach or suggest each and every element of independent claim 10. Accordingly, the obviousness rejections of claims 10, 13-14, 16, and 19 are improper and must be reversed.

II. One of ordinary skill in the art would not attempt the extensive modification of Kenigsberg's water-infusing diagnostic tool for use in a gastroesophageal track when contemplating a device for measuring blood pressure within a vascular structure specified in the pending claims at issue.

With the issuance of the June 22, 2007 office action, the Patent Office has now issued a total of eight (8) Office actions in this application dating from its filing date over five years ago on December 20, 2001. Appellant has been required to respond to each of those office

actions and in so doing has filed a total of three Requests for Continued Examination This has resulted in a protracted prosecution, not to mention an expensive one

It appears that no matter what amendment is made to the claims or viable argument is proffered, all patents issued by the U.S. Patent and Trademark Office will be searched for some reference which, in isolation, discloses some structure which purportedly resembles the newly claimed feature. Failing to find that, the all encompassing argument that it would be obvious to modify the primary reference to arrive at the claimed subject matter will be made. Clearly neither of those grounds for rejection is appropriate because none of the references cited by the Examiner is in the same or reasonably pertinent field of this application. It is well settled that only pertinent art can be utilized in an obviousness rejection:

> In order to rely on a reference as a basis for rejection of the applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.

In re Oetiker, 24 U S.P.Q 2d 1443, 1445 (Fed. Cir 1992).

The main reference upon which the Examiner has maintained his rejections throughout the five plus years of prosecution of this application is the Kenigsberg patent, which as discussed earlier is not at all related to the field of endeavor of the this application, but rather is a device for measuring pressure proximate to the sphincter between the esophagus and the stomach Kenigsberg's device has a multi-tubed structure including the sheath (12), the elongated tube (22) slidably and concentrically disposed within the sheath (12), and the first and second tubular members (32, 38) disposed parallel on the exterior surface of the sheath

As shown in Fig 2, the cross section of Kenigsberg's device includes a large central circle (12) with a concentric circle (22) therein, and first and second circles (32, 38) above

and below those concentric circles Each of those tubes are also of a different length and are necessarily so in that they need to reach to different depths within the human body, namely, to the esophagus above the sphincter, to the sphincter itself, and to the stomach below the sphincter. In use, water is steadily infused through the elongated member (22) and the tubular members (32, 38) into a patient's body while the resistance of the outflow of the infused water is recorded (col. 4, line 38-51) Kenigsberg is completely silent with respect to significance of the distal profile of the device presumably because the device is inserted through a spatially forgiving gastroesophageal track (44) with no apparent occlusions to navigate through or turns to negotiate (FIG 3).

The medical device specified in the claims at issue, on the other hand, directly measures the pressure within a vascular structure and is designed for introduction into small blood vessels, mainly arteries, where it is desired to perform an angioplasty and where the claimed device would be particularly useful in measuring blood pressure on both sides of a stenosis. If blood pressure differential between the two sides is of a sufficient level it would be deemed appropriate for an angioplasty to be performed, and if not, angioplasty should be avoided

Hence, the claimed medical device is designed to be navigated through clotted blood vessel, as illustrated in FIGs 1-3 of this application. One structural feature which allows for the claimed device to perform this function is its circular distal profile recited in each of the rejected claims. As discussed above, such structural feature is not specifically described in the specification or illustrated in the drawings of Kenigsberg. The Examiner nevertheless has relied upon the nebulous wording of the Kenigsberg specification stating that its structure "could be modified" to extensively reconstruct Kenigsberg's device in hindsight of the claimed device. Appellant respectfully submits that most specifications include that hopefully broadening language, but the Examiner and the Patent Office must apply some

degree of reasonableness to the level to which a disclosed structure can be reasonably assumed to be considered by the inventor and fall within that potential modification range. Clearly, a structure which uses different tubes to measure different pressures along an unclogged and linear length extending from the esophagus through the sphincter into the stomach, and which states that individual tubes are necessary for doing so, will not have a circular distal profile.

Presumably realizing the weakness in his argument, the Examiner is now citing the Peacock, III which by our count is the seventh individual reference the Examiner has used to reject the claims at issue throughout its five plus years of prosecution. Once again, the Examiner has embarked on a wide band search for a reference regardless of its individual field of endeavor which has at least one sentence or figure disclosing an individual claim element in isolation. Here, the Examiner sought to find a reference having a multi-tubed apparatus having an overall external configuration of a circle. In so doing, he is choosing to reject the claimed device based on a device used in open-heart bypass surgery to allow for a portion of aorta to be isolated and operated upon while still allowing circulation through the body.

How this is in any way related to measuring blood pressure on first and second sides of an occlusion to determine if angioplasty is needed, is not understood. Clearly tubes within tubes have been known for decades. The Examiner could have cited any one of dozens of patents disclosing such a mechanical feature ranging from automotive manifolds to vacuum cleaners. If this were the only limitation to which the Examiner must abide, his argument would succeed, however, the patent laws are written in a different way Instead, the Examiner must cite references which are within the same or reasonably pertinent field of endeavor, and which provide some motivation or suggestion to be combined or modified to arrive at the pending subject matter *See In re Oetiker, supra*. *See* also footnote on page 9.

As stated above, Kenigsberg is related to a gastroesophageal device which is multi-tubed and since the esophagus itself is a relatively large diameter lumen, a sleek design having tubes nested within others is not necessary. The newly cited Peacock, III reference is equally lacking. It is for use in open heart surgery. Introduction through small diameter lumens in the body is not sought in that the chest cavity itself is open during such a procedure, the ribs are spread, and the heart is directly accessed. Rather, Peacock, III is directed to a conduit for allowing the blood to circulate through the body while that open heart bypass surgery is being performed.

Neither of the references cited by the Examiner monitors blood pressure on two sides of a stenosis. In addition, there is no suggestion or motivation to combine the references to arrive at the claimed invention The first is directed to a gastroesophageal diagnostic device and the second is directed to a heart bypass device. To argue that such disparate references somehow would suggest the teaching of a low profile medical device with a circular distal profile for use in angioplasty is overreaching at best, absurd at worst

Thus, Appellant respectfully submits that one of ordinary skill in the art would not attempt the extensive modification of Kenigsberg's water-infusing diagnostic tool for use in a gastroesophageal track when contemplating a device for measuring blood pressure within a vascular structure specified in the pending claims at issue. Appellant further submits that the Examiner erred in relying on the non-obvious modification of the Kenigsberg reference to reject the claims at issue The rejections appealed herein are therefore improper and must be reversed

In light of the foregoing, Appellant respectfully submits that the appealed rejections are improper and must be reversed by the Board of Appeals because a *prima facie* case of obviousness is not established by the combination of the references proposed by the

Examiner and because none of the reference relied upon by the Examiner in making the appealed rejections is within the same or reasonably pertinent field of this application.

Dated: October 19, 2007

Respectfully submitted,

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VIII. CLAIMS APPENDIX

10 (Previously Presented) A device for measuring blood pressure in a vascular structure, comprising:

a tubular sheath sized for insertion into the vascular structure, the tubular sheath including an open proximal end, a closed distal end, at least two axially spaced apart openings in a sidewall thereof, and an inside peripheral surface,

an elongated tube disposed within the tubular sheath and including an open proximal end, a closed distal end, a single opening in a sidewall thereof and an outside peripheral surface engaging the inside peripheral surface of the tubular sheath about the entire outside peripheral surface of the elongated tube,

the elongated tube being frictionally received within the tubular sheath thereby allowing the opening of the elongated tube to be selectively aligned with one of the axially spaced apart openings of the tubular sheath at a time and so that engagement between the inside peripheral surface of the tubular sheath and the outside peripheral surface of the elongated tube substantially prevents fluid communication between the inside peripheral surface of the tubular sheath and the outside peripheral surface of the elongated tube and through the tubular sheath, and

a pressure transducer in fluid communication with the elongated tube proximal end so that blood from the vascular structure is communicated to the pressure transducer when the elongated tube opening is aligned with one of the tubular sheath openings, thereby to directly measure the blood pressure;

wherein the blood pressure measuring device has a distal portion that is inserted into the vascular structure, and wherein an exterior surface of the distal portion of the blood pressure measuring device has a cross-sectional profile of a single circle.

13. (Previously Presented) The pressure measuring device of claim 10 wherein the proximal end and the distal end of the tubular sheath define a first length,

the proximal end and the distal end of the elongated tube define a second length,

the second length being greater than the first length so that the proximal end of the elongated tube is disposed outside of the proximal end of the tubular sheath,

the elongated tube further comprising two markings, one of the markings of the elongated tube being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings of the elongated tube being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other of the openings of the tubular sheath

14 (Original) The pressure measuring device of claim 13 wherein at least one distal end of the tubular sheath or elongated tube comprises a radiopaque marker at a distal end thereof

16. (Previously Presented) A device for measuring blood pressure in a vascular structure, comprising:

a tubular sheath sized for insertion into the vascular structure, the tubular sheath including an open proximal end, a closed distal end, and at least two axially spaced apart openings in a sidewall thereof, and an inside peripheral surface,

an elongated tube disposed within the tubular sheath and including an open proximal end, a closed distal end and a single opening in a sidewall thereof, and an outside peripheral surface radially engaging the inside peripheral surface of the tubular sheath about the entire outside peripheral surface of the elongated tube,

the elongated tube being slidable within the tubular sheath thereby allowing the opening of the elongated tube to be selectively aligned with one of the axially spaced apart openings of the tubular sheath at a time,

the proximal end and the distal end of the tubular sheath define a first length,

the proximal end and the distal end of the elongated tube define a second length,

the second length being greater than the first length so that the proximal end of the elongated tube is disposed outside of the proximal end of the tubular sheath,

the elongated tube further comprising two markings, one of the markings of the elongated tube being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings of the elongated tube being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other of the openings of the tubular sheath, and

a pressure transducer in fluid communication with the elongated tube proximal end so that blood from the vascular structure is communicated to the pressure transducer when the elongated tube opening is aligned with one of the tubular sheath openings, thereby to directly measure the blood pressure;

wherein the blood pressure measuring device has a distal portion that is inserted into the vascular structure, and wherein an exterior surface of the distal portion of the blood pressure measuring device has a cross-sectional profile of a single circle

19. (Original) The pressure measuring device of claim 16 wherein at least one of the elongated tube or tubular sheath comprises a radiopaque marker at a distal end thereof

IX. EVIDENCE APPENDIX

An Evidence appendix is not included as no evidence and pursuant to § 1 130, § 1 131 or §1 132 or any other evidence entered by the Examiner and relied upon appellant in the appeal was ever submitted

X. RELATED PROCEEDINGS APPENDIX

A related proceedings appendix is not included as no related decisions rendered by a court or the Board in any proceedings identified pursuant to 37 C.F.R. §41.37 (c)(1)(ii) exists.